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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/607,035	06/25/2003	Clarence Nathaniel Ahlem	202.2D4	6394

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EXAMINER	
BADIO, BARBARA P	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 02/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/607,035	AHLEM ET AL.	
	Examiner	Art Unit	
	Barbara P. Badio, Ph.D.	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *50 and 54-76* is/are pending in the application.

4a) Of the above claim(s) *54,56,58,60,63,65 and 67-76* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *50,55,57,59,61,62,64 and 66* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

First Office Action on the Merits

Election/Restrictions

1. Applicant's election of Group II, treatment of inflammation associated with asthma and the compound of 3α,16β,17β-trihydroxy-5α-androstane in the reply filed on December 27, 2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Based on applicant's election of Group II, Claims 68-76 stand withdrawn from further consideration as being drawn to a nonelected invention. Based on applicant's elected compound, i.e., 3α,16β,17β-trihydroxy-5α-androstane, Claims 50 and 54-67 will be examined in the present application according to MPEP § 803.02 to the extent they read on Group I as defined under paragraph 2 of the previous Office Action. Therefore, claims 54, 56, 58, 60, 63, 65 and 67 stand withdrawn from further consideration as being drawn to a nonelected species. Claims 50, 55, 57, 59, 61, 62, 64 and 66 stand rejected as indicated below.

3. For the record, the generic group that will be examined in the present application is as follows:

Claims 50 and 54-67, drawn to a method of treating inflammation utilizing compounds as defined by claim 50 wherein R^7 is $-CH_2-$ or $-CHR^{10}-$; R^8 is $-CH_2-$ and R^9 is $-CH_2-$ or $-CHR^{10}-$ and the other R groups are as defined by the said claim.

Note: The claims will be examined as stated above in #2.

4. The examiner notes the group defined by applicant on page 8 of the response filed December 27, 2004. However, as indicated in the restriction requirement on page 7, because of the plethora of classes and/or subclasses in which the claimed compounds of said defined group fall, a serious burden would be imposed on the examiner to perform a complete search of the defined areas.

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 50, 57, 61 and 62 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 20-22

of copending Application No. 10/607,415. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both encompass the treatment of inflammatory diseases, such as asthma, utilization similar compounds. The difference is in the scope the claimed compounds recited by each set of claims, i.e., the above-mentioned copending application is limited to compounds wherein R^4 is =O or =S. However, both applications recite compounds wherein R^1 is an ester, thioester, ether or thioether; R^2 is H, -OH or -SH; R^3 is OH, ester, ether, thioester or thioether and R^4 is =O or =S (see for examples page 54, lines 16 and 24 of the present specification, compounds 5.1.8.1 and 5.2.9.1, respectively). Therefore, it would have been obvious to select any of the compounds of the instant invention, including those recited by copending Application No. 10/607,415, with the reasonable expectation that the compounds would be useful in treating inflammation as recited by both applications.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

7. Claims 50, 55, 57, 59, 61, 62, 64 and 66 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 30-33 of copending Application No. 10/728,400. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both encompass the treatment of inflammatory diseases, such as asthma, utilization similar compounds. The difference is in the scope the claimed invention, i.e., unlike the above-mentioned copending application, the present application is limited to treatment

of inflammatory disorders. However, both applications encompass applicant's elected compound, i.e., 3α,16β,17β-trihydroxy-5α-androstane (see page 91, line 22 of the above-mentioned copending Application, compound 1.1.3.9) and, thus, it would have been obvious to the skilled artisan to select any of the species of the instant invention, including those recited by the copending application, with the reasonable expectation the compounds would be useful in treatment of inflammatory conditions as recited by both applications.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

8. Claims 50, 57, 61, 62 and 66 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 19-21 of copending Application No. 10/949,694. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both encompass the treatment of inflammatory diseases, such as asthma, utilization similar compounds. The difference is in the scope of the claimed invention. However, both applications encompass 3α,16α-dihydroxy-17-oxoandrostane (see claim 67 of the present application and claim 5 of the copending application). Therefore, it would have been to the skilled artisan to select any of the species of the instant invention, including those recited by the copending application, with the reasonable expectation the compounds would be useful in treatment of inflammatory conditions as recited by both applications.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 50 and 57 are rejected under 35 U.S.C. 102(b) as being anticipated by Daynes et al. (US 5,532,230).

Daynes et al. teaches reduction of adult respiratory distress syndrome utilizing DHEA or derivatives thereof, such as 3,16-dihydroxy-17-oxo-androstane and the 5-ene derivative (see the entire article, especially col. 8, line 27-col. 9, line 4; col. 12, lines 4-8; col. 17, lines 23-30; claim 16). The method of use taught by the reference is encompassed by the instant claims.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claims 50, 55, 57 and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daynes et al. (US 5,532,230).

Daynes et al. teaches reduction of adult respiratory distress syndrome utilizing DHEA or derivatives thereof, such as 3,16-dihydroxy-17-oxo-androstane and the 5-ene derivative (see the entire article, especially col. 8, line 27-col. 9, line 4; col. 12, lines 4-8; col. 17, lines 23-30; claim 16). .

The instant claims differ from the reference by reciting compounds not exemplified by Daynes, i.e., compounds having a 17-hydroxy- group. However, Daynes teaches R^1 is oxo or hydroxyl. Thus, it would have obvious to one having ordinary skill in the art at the time of the present invention to modify the compound(s) exemplified by the reference making the 17-hydroxyl derivative of 3,16-dihydroxy-17-oxo-androstane and its 5-ene derivative with the reasonable expectation that the compound(s) would be useful in reducing adult respiratory distress syndrome as taught by Daynes. The motivation would be based on the desire to make additional compounds as taught by the reference for treatment of adult respiratory distress syndrome.

Telephone Inquiry

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary L. Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Barbara P. Badio, Ph.D.
Primary Examiner
Art Unit 1616

BB
February 2, 2005